Supreme Court, U.S.
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No. 03-

IN THE

Supreme Court of the United States

MEDINOL LTD.,

Petitioner,

v.

JOHNSON & JOHNSON, CORDIS CORPORATION, and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED FOR REVIEW

QUESTION 1

In the decision below, and again in the only subsequent case on the same point, the U.S. Court of Appeals for the Federal Circuit has upset the entire statutory scheme for evaluating the validity of patents based on publicly available information about the prior art. The Court announced a new doctrine holding that an otherwise valid patent can be found obvious and invalidated under 35 U.S.C. § 103 by relying not just on prior art under 35 U.S.C. § 102, but also on secret drawings of an abandoned design, which were never publicly available, and which are not prior art under any provision of 35 U.S.C. § 102.

This is new law that conflicts with the patent statute and threatens to undermine fundamental policies of the patent system. Accordingly, the first question presented is:

Whether proof that the claimed subject matter of an otherwise valid U.S. patent would have been obvious under 35 U.S.C. § 103 can be based on secret and abandoned drawings that are not part of the prior art under 35 U.S.C. § 102?

QUESTION 2

In the decision below, the Federal Circuit declined to review allegedly prejudicial claim construction errors based on the illogical new legal presumption that they must be deemed harmless to the obviousness issue simply because they narrowed, rather than broadened, the asserted claims.

This decision conflicts with the fundamental right of a patentee to have appellate review of the crucial question of claim construction. Accordingly, the second question presented is:

Whether claim construction errors (i) which materially changed the obviousness question put to the jury, (ii) which had the effect of eliminating important objective evidence of nonobviousness, and (iii) which likely changed the jury's obviousness verdict, can be ignored and assumed to be harmless with respect to the obviousness issue only because they narrowed, rather than broadened, the asserted claims?

PARTIES TO THE PROCEEDING

The parties to the proceeding in the court of appeals were the plaintiff-appellant Medinol Ltd. ("Medinol"), and the defendants-appellees Johnson & Johnson ("J&J"), Cordis Corporation ("Cordis"), and Johnson & Johnson Interventional Systems, Inc. ("JJIS") (collectively "J&J/Cordis"). Plaintiffs Scimed Life Systems, Inc. ("Scimed"), Boston Scientific Corporation ("BSC") and Boston Scientific Scimed, Inc. ("BSSI") (collectively "BSC/Scimed") were parties to the proceeding in the district court.

RULE 29.6 STATEMENT

Petitioner Medinol Ltd. does not have any parent corporation. The only publicly held company that owns 10% or more of petitioner Medinol Ltd.'s stock is Boston Scientific Corporation.

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Petitioner Medinol Ltd. ("Medinol") respectfully petitions for a writ of certiorari to review the judgment of the U.S. Court of Appeals for the Federal Circuit in this case.

OPINIONS AND ORDERS BELOW

The opinion of the court of appeals (App. 1a-19a) is unreported, but is available at *Scimed Life Systems, Inc. v. Johnson & Johnson*, 87 Fed. Appx. 729, 2004 U.S. App. LEXIS 510 (Fed. Cir. Jan. 14, 2004). The opinion of the district court on post-trial motions (App. 20a-59a) is reported at *Scimed Life Systems, Inc. v. Johnson & Johnson*, 225 F. Supp. 2d 422 (D. Del. 2002); the order of the district court denying reconsideration (C.A. App. A1-A2) is unreported. The order of the district court on claim construction (App. 62a-70a) is unreported. The opinion of the district court on summary judgment motions (*Id.* at 71a-82a) is unreported, but is available at *Scimed Life Systems, Inc. v. Johnson & Johnson*, 2001 U.S. Dist. LEXIS 12862 (D. Del. Aug. 15, 2001).

STATEMENT OF JURISDICTION

The judgment of the court of appeals was entered on January 14, 2004. App. 1a. A timely petition for rehearing and rehearing *en banc* was denied on February 23, 2004. *Id.* at 85a-86a. This Court has jurisdiction to review on a writ of certiorari the judgment of the court of appeals under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS

35 U.S.C. § 102(a), (b), (e), (f) and (g) provide:

> § 102. Conditions for patentability; novelty and loss of right to patent
>
> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this

or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

* * *

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or

(f) he did not himself invent the subject matter sought to be patented, or

(g) (1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made

> by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.
>
> * * *

35 U.S.C. § 103(a) provides:

> § 103. Conditions for patentability; non-obvious subject matter
>
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

STATEMENT OF THE CASE

This petition presents two important questions of patent law and policy.

First, in its decision below and in the one subsequent case on the same point, *National Steel Car, Ltd. v. Canadian Pacific Railway Co.*, 357 F.3d 1319 (Fed. Cir. 2004), the Federal Circuit has suddenly promulgated a new and potentially destructive patent defeating doctrine that allows a patented invention to be invalidated under 35 U.S.C. § 103 by relying on contemporaneous secret drawings of an abandoned design, which are not prior art under 35 U.S.C. § 102, to show that a combination of prior art elements would have been obvious to a person of ordinary skill in the art.[1]

Second, in its decision below, the Federal Circuit refused to consider or review claim construction errors which prejudicially changed the obviousness question put to the jury, both by narrowly misdescribing and trivializing the invention that the jury was asked to compare with the prior art, and by eliminating the applicability of important objective evidence of nonobviousness ("secondary considerations"). The objective evidence that was effectively eliminated included evidence that Cordis needed a replacement design for its obsolete product, that it evaluated the design of Medinol for nearly a year, that it twice tried designs of its own which failed, and that it finally adopted Medinol's patented design, without paying for it, after its predecessor's division president recommended purchasing the rights to Medinol's patented design for $335 million.

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1. Both Medinol and National Steel Car, Ltd. petitioned the Federal Circuit for rehearing and rehearing *en banc* in their respective appeals, and, given the similar issues, counsel for both parties requested that rehearing *en banc* in each case be heard together with rehearing *en banc* in the other case. Both petitions were denied, and both decisions stand as settled law by the Federal Circuit, which has exclusive appellate jurisdiction over patents. 28 U.S.C. § 1295(a)(1).

Moreover, it is clear that this objective evidence of nonobviousness would likely have changed the obviousness verdict on the claims invalidated, because the validity issues were extremely close. The jury found the four claims asserted against Cordis' primary accused product to be invalid and not infringed, but it found another claim of nearly identical scope to one of the invalidated claims to be valid and infringed. The only significant difference between these two claims (one found valid and one found invalid) was that the valid claim was asserted against a product which was found to infringe, and Cordis could not avoid the applicability of objective evidence of nonobviousness. In contrast, the claims found invalid were also found not infringed (based on the erroneous claim construction), permitting Cordis to argue that the objective evidence of nonobviousness was not applicable.

A. The Medinol Invention and NIR Stent

The patents in suit are for an important and valuable invention in the field of coronary stents.[2] Petitioner Medinol is a small innovative company that set out in 1994 to design an improved coronary stent. At that time, the concept of balloon expandable stents was known, but the existing stents had significant limitations. Stents had to be flexible during delivery on the balloon catheter in order to travel around curves in the artery. After expansion, stents needed to be strong and stable and to provide uniform coverage or scaffolding without gaps in order to adequately support the diseased portions of the artery to be held open. Stents with good coverage also needed to be expandable uniformly with a mechanism to compensate for significant shortening along their length during expansion, in

2. Stents are small metal cylindrical cage-like devices that are implanted in narrowed or blocked coronary arteries (or other vessels) to hold them open, like scaffolding in a tunnel, to improve blood flow. A stent is delivered through the artery to the treatment site on a balloon at the tip of a catheter, where it is expanded by inflating the balloon and then left in place when the balloon catheter is deflated and withdrawn. C.A. App. A1304-12.

order to ensure accurate placement and coverage and to avoid longitudinally scraping the artery during expansion. C.A. App. A1315-17; A1440-41. The best stent designs in the prior art had some of these properties, but always at the expense of others.

Medinol's patented invention was an important breakthrough because it combined for the first time all of these desirable properties – flexibility during delivery, strength and uniform coverage without gaps after expansion, and uniform expansion without significant foreshortening. *Id.* at A1317-19; A1329-39; A1445-52; A1697-98. Medinol's invention became the basis for the NIR stent, which was manufactured by Medinol and sold under license by the co-plaintiff in the district court, Boston Scientific Corporation ("BSC"). The NIR was a dramatic success when it was launched both in Europe and the U.S., with U.S. sales in the first full year exceeding $370 million. *Id.* at A9307.[3]

B. Cordis' Need For a New Stent Design to Replace its Obsolete Design

At the time of Medinol's invention in 1994, Cordis' predecessor division at Johnson & Johnson – Johnson & Johnson Interventional Systems, Inc. ("JJIS") – was already on the market with its own more primitive design for a balloon expandable stent known as the Palmaz-Schatz stent. The Palmaz-Schatz stent was successful while it was the only stent on the market, but JJIS and Cordis recognized that it was inflexible and would rapidly become obsolete when newer stents came on the market. C.A. App. A1322-25; A1437-40; A1629-31; A1640-47; A1654-61. Accordingly, JJIS and Cordis began searching for a replacement stent. *Id.* at A1629-31; A1640-47; A1654-61.

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3. Medinol and BSC are now engaged in litigation against each other involving the contract between them and other issues, and Medinol has since sued BSC for infringement of counterparts of the patents in suit in Europe. BSC did not join in the appeal below.

C. Cordis' Favorable Evaluation of and Plan to Purchase Medinol's Stent Design

Medinol's NIR stent and patented technology were first evaluated by JJIS in 1994-95. *Id.* at A1457-73. After its evaluation, JJIS' president concluded that the Palmaz-Schatz stent had a "serious disadvantage" of inflexibility, and that Medinol's design was "unique" and represented "flexible stent technology that [JJIS] had been unable to develop in 18 months or so of trials and developments." *Id.* at A1470; A12505-15; A1534; A1630; A1645-46; A12814-16. He strongly recommended a $335 million deal with Medinol consisting of a $105 million license and an option to buy the patents and technology for $230 million. *Id.* at A12814-16. In September 1995, Cordis and Medinol executed a "letter of intent" granting Cordis an option to acquire Medinol's patent and technology assets for $335 million. *Id.* at A1471-73; A12438-44. After a management change, however, Cordis sought to renegotiate the terms of the option and paid $5 million for a three week extension of time to do so, but the parties did not enter into a final agreement. *Id.* at A1478-79. Thereafter, Medinol entered into an agreement to market the NIR stent with BSC. *Id.* at A1483.

D. Cordis' Failure to Develop Its Own Replacement Stent Designs

By 1997, before Medinol and BSC entered the U.S. market with the NIR stent in 1998, Cordis' market share had dwindled due to stiff competition from new and improved stents by two other competing manufacturers. *Id.* at A1534. Cordis attempted to regain its market share by twice trying and twice failing to design and develop its own improved stents – the Crown and Crossflex stents – both of which had significant limitations and were never well accepted. *Id.* at A1339-41; A1534.

E. Cordis' Adoption of Medinol's Patented Design

After failing twice to develop its own improved stent to recover its lost market share, Cordis returned to the Medinol technology that it had favorably evaluated in 1994-95. In 2000, it launched its new BX Velocity stent, which was extremely close in design to the Medinol NIR stent and had the same combination of desirable properties. *Id.* at A1342-46; A1523-31; A1962-65; A12934-36; A12940-53; A9057-60. The BX Velocity was an instant success and Cordis quickly recovered its lost market share.

F. The Secret Drawings of the Abandoned Burmeister Design

Unknown to either Medinol or Cordis at the time, other stent designers at Scimed Life Systems, Inc. (which was later purchased by BSC) were contemporaneously working on a bimetal stent using a number of different stent designs, one of which was arguably similar, but not the same as, the NIR design. C.A. App. A732. The Scimed inventors (Burmeister, *et al.*) filed a patent application on the bimetal stent including various designs, but after testing the design that was arguably similar to the NIR, they concluded it would not work and abandoned it. *Id.* at A732-33; A13027-52. They later abandoned their original application and filed a continuing application which included the other designs, but which omitted the design that was arguably similar to the NIR design. *Id.* at A732; A12778-813. This later application issued as a patent, but did not include the abandoned design similar to the NIR. The drawings of this abandoned design (Figures 13, 14(a) and (b) of the original abandoned application) were never published or made available to anyone else in the art. App. 79a-80a. They only came to light because, after Scimed (as a subsidiary of BSC) became a party in the case, the drawings of this abandoned design were produced in discovery. *Id.* at 80a.

G. The Proceedings Below

Medinol and BSC/Scimed sued Cordis for infringement of three Medinol patents,[4] all of which have the same disclosure and stem from the same original patent application filed on July 28, 1994. Four representative patent claims were asserted against Cordis' BX Velocity stent and one claim was asserted against Cordis' less successful Crown and Corinthian stents.

Prior to trial, the district court held a claim construction hearing and issued its interpretation of several disputed claim terms, including the interpretations challenged by Medinol in the Federal Circuit. App. 62a-70a. Several of the district court's claim constructions added extraneous limitations to the claims, which had the effect of making those claims narrower. These constructions were pivotal, because they were the sole basis for Cordis' non-infringement defenses for the BX Velocity at trial.[5] One of the district court's rulings made one of the asserted claims broader.

After a two week trial and two days of deliberations, the jury issued a split verdict. The jury found that all four claims asserted against the BX Velocity were not infringed, based on the district court's overly narrow claim construction, and also found that these four claims were all invalid for obviousness. In contrast, the jury found that the sole claim asserted against the Crown and Corinthian stents was infringed by the Corinthian (but not by the Crown) stent, and that this claim was not invalid for obviousness. C.A. App. A8788-800.

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4. The district court had jurisdiction over this action for patent infringement under 28 U.S.C. § 1331 and § 1338(a).

5. Specifically, the district court improperly added a requirement that one component of the patented design have a "generally horizontal" or "longitudinal" alignment parallel to the stent axis. App. 62a-70a. This requirement was added in one form or another to every claim. Cordis exploited this erroneous limitation by arguing that the corresponding element of the BX Velocity design was "diagonal" and not "generally horizontal" or "longitudinal" parallel to the axis. C.A. App. A2799-811.

Medinol moved both for judgment as a matter of law (JMOL) based on insufficient evidence, and for a new trial on both the validity and infringement issues. The district court denied both motions (App. 20a-59a) and refused to reconsider its decision (C.A. App. A1-A2).

Medinol then appealed to the Federal Circuit seeking appellate review of the denial of both its JMOL and new trial motions. In its appeal from denial of the JMOL motion, Medinol argued that the claims (when properly construed) were literally infringed and that there was insufficient evidence (including specifically insufficient evidence of a motivation to combine prior art elements) to support the obviousness verdict for the four claims invalidated. In its appeal from denial of the new trial motion, Medinol argued that the district court's claim construction errors (specifically including the narrowing claim construction errors) had a prejudicial impact on both obviousness and infringement issues.

The Federal Circuit affirmed the denial of Medinol's JMOL motion, finding that there was legally sufficient evidence to support the verdict of obviousness. App. 1a-19a. In particular, after concluding that each of the individual elements of the patented invention was contained in the prior art, the Federal Circuit held that there was legally sufficient evidence that it would have been obvious to combine the individual elements, because such elements had been combined by the Burmeister inventors in the drawings for the design which they abandoned (Figures 13, 14(a) and 14(b) of the original abandoned application). *Id.* at 17a-19a. The Federal Circuit conceded that the Burmeister abandoned drawings had been found by the district court to be not publicly accessible and not part of the prior art, and that that finding had not been challenged on appeal. *Id.* at 17a n.1. Even though they were not part of the prior art, however, the Federal Circuit relied on them to show that the combination was obvious by imputing knowledge of their content to a hypothetical person of ordinary skill in the art, stating that the question was what such an artisan "would have gleaned"

from such abandoned drawings, and/or would have learned from "inspect[ing]" them. *Id.* at 18a-19a.

The Federal Circuit also affirmed the denial of Medinol's new trial motion, concluding in summary fashion that "the district court did not abuse its discretion when it denied the plaintiffs' motion for new trial." *Id.* at 19a. But the Federal Circuit did not review any of the narrowing claim construction errors that were a principal ground for the new trial motion.[6] Nor did either the district court (which declined to reconsider its own claim construction rulings (App. 42a, n.2)) or the Federal Circuit review any of these errors to determine whether or not, if erroneous, the resulting errors in legal instructions to the jury would have been prejudicial to the outcome.

As a result, Medinol has been denied any review of the narrowing claim construction errors and/or their prejudicial impact on the obviousness verdict.

REASONS FOR GRANTING THE PETITION

The patent system works as an important incentive to encourage and reward investment in new developments which are made available to the public. For the system to work effectively, patent owners and prospective investors need to make important judgments about the strength and scope of patents, and they can only do so based on publicly available information about the prior art. The statutory scheme of Section 102 and Section 103 supports this purpose, even though carefully limited categories of prior art, *e.g.*, Sections 102(e) and (g), may be secret temporarily.

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6. The Federal Circuit considered only the one claim construction error broadening one claim, concluding that this was the only alleged error that went to the issue of validity. *Id.* at 14a. The court declined to review any of the other alleged claim construction errors and declined to address any of Medinol's contentions as to infringement, or as to the prejudice of making the objective evidence of nonobviousness inapplicable, because it held there was substantial evidence in the record to support the obviousness verdict. *Id.* at 13a, 14a.

The Federal Circuit's new doctrine threatens to undo the entire framework for evaluating patents based on publicly available information, by allowing for the first time patents to be invalidated based on secret and abandoned drawings which do not qualify as prior art under any section of the statute.

I. *Certiorari* Should Be Granted Because The Decision Below Conflicts With The Patent Statute And Undermines Fundamental Policies Of The U.S. Patent System.

A. There Is No Statute or Case Law Precedent For the Federal Circuit's New Reliance on Secret and Abandoned Drawings, Which Are Not Prior Art, to Show Obviousness Under Section 103.

Section 103 of the patent statute requires that the obviousness of an invention be judged by comparing the claimed invention to the prior art as defined in Section 102. The statute provides:

> § 103. Conditions for patentability; nonobvious subject matter
>
> > (a) A patent may not be obtained though the invention is not identically disclosed or described *as set forth in section 102* of this title, if the differences between the subject matter sought to be patented *and the prior art* are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. . . .

35 U.S.C. § 103(a) (emphasis added); *see also Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).[7]

7. The statutory hypothetical person of ordinary skill of Section 103 is deemed to possess ordinary skill in the art and is presumed to know all the prior art, as defined in Section 102. *See Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1453-54 (Fed. Cir. 1984).

The prior art against which the obviousness of the invention is to be judged is defined in Section 102 to be patents, publications and *knowledge available to the public* before the invention or filing date, with only very limited statutory exceptions for temporarily "secret" prior art, none of which are material here, *i.e.*, earlier filed issued U.S. patents under Section 102(e); work of others that was privately available to the inventors under Section 102(f); and prior inventions that were not abandoned, suppressed or concealed under Section 102(g). *See* 35 U.S.C. § 102(a), (b), (e), (f) and (g); *see also OddzOn Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1402-04 (Fed. Cir. 1997).

In order to avoid improper hindsight, the Federal Circuit and its predecessor courts have consistently held that a patented invention would not have been obvious to the hypothetical person of ordinary skill on the date of invention unless there is a "clear and particular" showing of a teaching, suggestion or motivation to combine the various prior art references to arrive at the patented invention. *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 664 (Fed. Cir. 2000); *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999); *In re Shaffer*, 229 F.2d 476, 479 (CCPA 1956).

Prior to its decision in the case under review, the Federal Circuit had also consistently held that this teaching or motivation to combine the prior art had to come *from the prior art* – either from the prior art references that were themselves being combined or from "the knowledge generally available" to those of ordinary skill:

> To properly combine references A and B to reach the conclusion that the subject matter of a patent would have been obvious, case law requires that there must have been some teaching, suggestion, or inference *in either reference A or B, or both, or knowledge generally available to one of ordinary skill in the relevant art*, which would have led one skilled in the art to combine the relevant teachings of references A and B.

Ashland Oil v. Delta Resins & Refractories, 776 F.2d 281, 297 n.24 (Fed. Cir. 1985) (emphasis added);[8] *see also, e.g., In re Jones*, 958 F.2d 347, 351 (Fed. Cir. 1992) (motivation may be found "in the knowledge *generally available* to one of ordinary skill in the art" (emphasis added)); *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988) (motivation may be found in the "knowledge *generally available* to one of ordinary skill in the art" (emphasis added)).

Contrary to its own settled precedent and the statutory categories of prior art, the Federal Circuit has for the first time, in the case under review and the one other subsequent decision on the subject, *National Steel Car, Ltd. v. Canadian Pacific Railway Co.*, 357 F.3d 1319 (Fed. Cir. 2004), relied on secret and unpublished drawings of an abandoned design that were *not* prior art as evidence that the motivation to combine was within the knowledge of the hypothetical person of ordinary skill.

1. The Decision Below

In the case under review, the Federal Circuit upheld the jury's obviousness verdict by finding that the secret drawings of the abandoned Burmeister design, which were not prior art, constituted legally sufficient evidence that the motivation to combine the prior art was within the knowledge of the hypothetical person of ordinary skill. App. 17a-19a. Although the Federal Circuit conceded that the drawings (Figures 13, 14a and 14b of the original abandoned application) had been previously determined by the district court to be "not publicly accessible" on the filing date and therefore "not prior art" (*Id.* at 17a n.1),[9] the Federal Circuit then erroneously treated

8. Although not relevant here, the motivation to combine may also sometimes be found in the nature of the problem to be solved. *Ruiz*, 234 F.3d at 665.

9. The district court granted Medinol summary judgment that Figures 13, 14a and 14b of the Burmeister application were not prior art to the Medinol inventions, stating:

> The Burmeister Application was abandoned and the relevant

(Cont'd)

these drawings as though they were prior art that was available to the hypothetical person of ordinary skill, in order to find the requisite motivation to combine. The Court stated:

> The question "is what a hypothetical ordinarily skilled artisan *would have gleaned from the [Burmeister application]* at the time that the patent application leading to the [patents in suit] was filed."

Id. at 18a (alteration in original) (citation omitted) (emphasis added). The Court went on to conclude (without any support):

> The jury had before it expert testimony that a person of ordinary skill in the art, on July 28, 1994, *would inspect the drawings of the Burmeister application* and conclude it disclosed a stent design that combined the claimed elements of the balloon expandable stent design taught by the patents-in-suit.

Id. at 18a-19a (emphasis added).[10]

This analysis is patently erroneous and contrary to both the statute and settled precedent, because the drawings of the Burmeister designs on which the Federal Circuit relied were secret and abandoned, and were not prior art. They were not available on the July 28, 1994 filing date of the Medinol application to the hypothetical person of ordinary skill in the

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> drawings were never revealed to the public, nor were they actually reduced to practice. The only reason the drawings are at issue now is because Scimed, licensed by Medinol, is a party to this action and produced the drawings in discovery. In the absence of a voluntary publication of the Burmeister Application, the drawings never would have surfaced as potential prior art.

App. 80a. This summary judgment ruling was not appealed by Cordis. *Id.* at 17a n.1.

10. In fact, contrary to this statement by the Federal Circuit, Cordis' expert actually testified that the Burmeister design did *not* contain all of the elements of the claimed invention and that it was *not* prior art. C.A. App. A2834-35.

art. No one (other than Burmeister) could have "inspected" them or "gleaned" anything from them.

2. The Decision in *National Steel Car, Ltd. v. Canadian Pacific Railway Co.*, 357 F.3d 1319 (Fed. Cir. 2004)

After its decision in the case under review, the Federal Circuit issued its decision in the *National Steel Car* appeal and once again relied on secret and unpublished drawings of abandoned designs by contemporaneous workers that were not prior art, as evidence that the motivation to combine the prior art was within the knowledge of the hypothetical person of ordinary skill. *See National Steel Car*, 357 F.3d at 1337-39.

The Federal Circuit again expressly stated that the unpublished drawings by the contemporaneous workers Lund and Prichard were evidence of a motivation to combine *even though they were not prior art*:

> [T]he district court erred as a matter of law insofar as it held that Mr. Lund's failure to share this drawing with others disqualifies the Lund drawing from being relevant to whether a motivation to combine Wagner and Udstad is implicit in the knowledge of one of ordinary skill in the art. The question at hand is not whether others learned of the Lund drawing, as it would be if we were determining the status of the Prichard disclosure as prior art.
>
> * * *
>
> Whether or not the Prichard disclosure is a prior art reference, it is evidence that can be used to demonstrate a motivation to combine implicit in the knowledge of one of skill in the art of rail car design.

Id. at 1338, 1339. This is flatly inconsistent with both the statute and settled precedent, which requires that the motivation to combine the prior art be found in the prior art, either in the specific references or in knowledge "generally available" to those of skill in the art. *See Ashland*, 776 F.2d at 297 n.24.

B. The Federal Circuit's New Reliance on Secret and Abandoned Drawings to Show Obviousness Conflicts with Fundamental Patent Policies Which Reward The Inventor Who Publishes His Invention by Patenting It and Which Presume That Two or More Inventors Can Simultaneously Make the Same Invention.

By invalidating patents based on secret and abandoned work that is not prior art, the Federal Circuit's decisions in the case below and in *National Steel Car* violate fundamental patent law policies that reward the inventor who publishes his invention by patenting it, even if the same invention was made earlier by another who abandoned it:

> [W]hen the possessor of secret art (art that has been abandoned, suppressed, or concealed) that predates the critical date is faced with a later-filed patent, the later-filed patent should not be invalidated in the face of this "prior" art, which has not been made available to the public. Thus, prior, but non-public, inventors yield to later inventors who utilize the patent system.

OddzOn Products, 122 F.3d at 1402; 35 U.S.C. § 102(g).

By assuming without proof or analysis that the earlier abandoned drawings were obvious and not an invention, the decisions below and in *National Steel Car* are also inconsistent with a basic premise of the U.S. "first-to-invent" patent system, which is that two or more contemporaneous but independent workers may both have the same inventive insight at the same time and both develop a patentable invention.[11]

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11. While contemporaneous work by others may be evidence that supports obviousness as a "secondary consideration" when coupled with other evidence, such as where numerous workers arrive at the same solution shortly after a need arises, there is no precedent for relying upon such work, when it is not in the prior art and presumed to be known, as evidence of a motivation to combine, absent other proof that (Cont'd)

Indeed, simultaneous (or nearly simultaneous) invention by two or more inventors is the entire premise of the interference statute, which determines priority among such competing inventors:

> Because the statute, 35 U.S.C. § 135, (establishing and governing interference practice) recognizes *the possibility of near simultaneous invention by two or more equally talented inventors working independently*, that occurrence may or may not be an indication of obviousness when considered in light of all the circumstances. In this instance, it clearly is not.

Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.2d 1452, 1460-61 (Fed. Cir. 1984) (citation omitted) (emphasis added) (rejecting evidence of contemporaneous work done after the invention as a "secondary factor" indicating obviousness) (*citing E.I. Du Pont de Nemours & Co. v. Berkley & Co.*, 620 F.2d 1247 (8th Cir. 1980) (Markey J. sitting by designation)).[12]

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such work was itself merely obvious and not inventive. Even as a secondary consideration, the mere fact that two workers arrive at the same or similar designs around the same time, without more, is not probative evidence of obviousness. There simply is no basis in law or in logic for presuming, as the Federal Circuit did here, that such contemporaneous work was obvious, especially in a case such as this one where the contemporaneous worker initially sought a patent on it.

12. Had an interference been declared between the Medinol application and the Burmeister application, the Medinol application would have prevailed because the Burmeister application was abandoned. *See* 35 U.S.C. § 102(g), § 135.

C. The Federal Circuit's New Reliance on Secret and Abandoned Drawings to Show Obviousness Conflicts with Fundamental Patent Law Principles Because It Necessarily Presumes that Persons Preparing Such Drawings Can Never Themselves Make a Patentable Invention.

The Federal Circuit's decisions in this case and *National Steel Car* are also flawed because they treat contemporaneous work by another as evidence of what would have been obvious to the hypothetical person of ordinary skill. By doing so, the Federal Circuit necessarily presumes that such work cannot be inventive, since an inventive design cannot be evidence that it would have been obvious to combine the elements within the prior art:

> [W]hen references are combined to negate patentability, it should also be considered whether one skilled in the art with the references before him could have made the combination of elements claimed *without the exercise of invention.*

In re Shaffer, 229 F.2d at 479 (emphasis added).

In the case below, the Federal Circuit simply assumed without explanation that the Burmeister drawings were not inventive. The court then proceeded to treat the drawings as if (despite their secrecy) they could be used as evidence of the knowledge of a hypothetical person of ordinary skill, either by analyzing what the hypothetical person would have "gleaned" from "inspecting" such abandoned work, or by imputing knowledge of such work to the hypothetical person based on the assumption that such work was obvious and not inventive.[13]

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13. The Federal Circuit's reliance in this regard on *Amazon. com,Inc. v. barnesandnoble.com, inc.*, 239 F.3d 1343 (Fed. Cir. 2001) (App. 18a) illustrates this error. Unlike the case here, the subject matter that could have been "gleaned" by the hypothetical person of ordinary skill in the *Amazon.com* case was contained in published prior art references, not secret unpublished work. *Amazon.com*, 239 F.3d at 1364 ("The relevant

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In *National Steel Car*, the Federal Circuit simply imputed the secret knowledge of Lund and Prichard – whom it found to have less than ordinary skill – to the hypothetical person of ordinary skill, by reasoning that someone of ordinary skill must know at least as much as one of less than ordinary skill:

> Lund's knowledge is relevant to determining the knowledge of one of ordinary skill of the art even if Lund's qualifications fell short of the background required of one of ordinary skill. *Something that has already been rendered obvious* to a relative newcomer in a field is probative of what would be obvious to someone who has been around for a longer period of time.
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> * * *
>
> [W]e are concerned only with whether the Lund drawing demonstrates that others in Mr. Lund's position (or a more experienced position) *would have considered it obvious* to combine the elements found in Wagner and Udstad.
>
> * * *
>
> Like Lund, Prichard is one of less than ordinary skill in the art employed within the relevant art. Thus, like Lund's testimony, Prichard's testimony is relevant to determining what was implicit in the knowledge of one of ordinary skill in the art.

National Steel Car, 357 F.3d at 1338, 1339 (citation omitted) (emphasis added). As the emphasized language makes clear, in doing so, the Court simply assumed without proof that the Lund and Prichard designs were obvious and not inventive.

The problem with the Federal Circuit's reasoning is that it presumes that contemporaneous work by someone of ordinary

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inquiry is what a hypothetical ordinarily skilled artisan *would have gleaned from the cited [prior art] references* at the time that the patent application leading to the '411 patent was filed." (emphasis added)).

skill is evidence of what would have been obvious to the hypothetical person of ordinary skill, based solely on the level of skill and training of that worker. By doing so, it necessarily presumes that such work cannot have been the result of the exercise of inventive skill, but instead must simply have been the obvious result of the exercise of ordinary skill. In other words, the Federal Circuit simply presumes that work by one of ordinary skill must always be routine and can never be inventive.

This is inconsistent with the fundamental premise of the patent system that anyone, regardless of education, skill or training, can at any given moment have an inventive insight and make a patentable invention. *See Kimberly-Clark*, 745 F.2d at 1454 ("Real inventors, as a class, vary in their capacities from ignorant geniuses to Nobel laureates."). The patentability standard of Section 103 asks only whether the invention itself would have been obvious in view of the prior art to one of ordinary skill, not whether the skill and training of the person who did the work was ordinary or extraordinary. The manner in which an inventor arrived at his or her invention, be it "from long toil and experimentation or from a flash of genius," has no bearing on whether the invention is patentable. *See* Reviser's Note to 35 U.S.C. § 103; 35 U.S.C. § 103(a) ("Patentability shall not be negatived by the manner in which the invention was made."). There is no basis for presuming that contemporaneous work is obvious based on *the ordinary level of skill of the worker* without analyzing whether *the work* itself was in fact obvious or inventive.

The logic of the Federal Circuit's presumption is plainly flawed and circular. One cannot look at the private, secret doing of a new thing by one of ordinary skill in the art as itself being evidence that it was within the ordinary skill of the art – for, by that test, no one could get a patent who was of ordinary (or less than ordinary) skill in the art, which conclusion is the antithesis of the patent system. If this were really the law, it would add a whole new layer of analysis (an amorphous one at best) because to determine whether a person was eligible for a patent one

would have to focus on and examine that person's pedigree (which would have to be superior to persons of ordinary skill in the art to be eligible to make a patentable invention) as distinct from the present focus on what it was that the person did. If it be the law that what a person of ordinary skill in the art does cannot be an invention but only evidence that the modification to do it was the ordinary skill of the art, then the mere fact that a person of ordinary skill has done it means it is not an invention and thus not patentable.

There is no rational basis for distinguishing two persons who have independently done the same thing at about the same time – saying that the first of ordinary skill who did it was only practicing ordinary skill because he had only ordinary skill, and saying that the second to do it would, but for the first one having independently done it, have made an invention (ignoring that he too had only ordinary skill).

Since there is no basis for assuming that the secret and abandoned Burmeister drawings in this case, or the secret and abandoned Lund and Prichard drawings in *National Steel Car*, were generated with only ordinary (as opposed to inventive) skill, and since these drawings are admittedly not part of the prior art, it is legally improper to rely upon them as evidence of obviousness under Section 103. Moreover, it will undermine the goals of the patent system, jeopardize issued patents whenever previously unknown secret and abandoned work is "discovered" in litigation, and generally make investment in patents more perilous and uncertain, if this Court allows the Federal Circuit to continue with its new doctrine of relying on secret and abandoned work to invalidate otherwise valid patents.

II. *Certiorari* Should Be Granted Because The New Assumption In The Decision Below Will Repeatedly And Unjustly Deny Patentees Appellate Review Of Legal Claim Construction Errors Which (Even Though They Narrow A Claim) Materially Impact An Obviousness Verdict.

A. The District Court's Claim Construction Errors, Which the Federal Circuit Refused to Review, Materially Changed the Obviousness Question Put to the Jury.

It is a fundamental principle in any case tried to a jury that a prejudicial legal error in a jury instruction is grounds for a new trial:

> [A]n error which relates, not to merely formal or technical matters, but to the substantial rights of the parties – *especially when embodied in the charge to a jury* – is to be held a ground for reversal, unless it appears from the whole record that it was harmless and did not prejudice the rights of the complaining party. In the present case the error in the charge could not but mislead the jury in reference to a material element necessary for its consideration . . . and it cannot be said from the whole record that the substantial rights of the United States were not prejudiced thereby. The judgments of the District Court should therefore have been reversed, and new trials granted.

United States v. River Rouge Improvement Co., 269 U.S. 411, 421 (1926) (citations omitted) (emphasis added).[14]

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14. *See also Fillippon v. Albion Vein Slate Co.*, 250 U.S. 76, 82 (1919) ("And of course in jury trials erroneous rulings are presumptively injurious, especially those embodied in instructions to the jury; and they furnish ground for reversal unless it affirmatively appears that they were harmless."); *Kotteakos v. United States*, 328 U.S. 750, 764-65 (1946); *LNC Invs. v. First Fid. Bank, N.A.*, 173 F.3d 454, 463 (2d Cir.

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In *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), this Court affirmed the Federal Circuit's *en banc* decision that the interpretation of patent claims is a question of law to be decided by the court, not the jury. *Id.* at 376, *aff'g*, 52 F.3d 967 (Fed. Cir. 1995) (*en banc*). Since claim construction is a question of law, the Federal Circuit has previously correctly assumed the obligation to review a district court's claim construction *de novo* on appeal. *See Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448, 1451 (Fed. Cir. 1998) (*en banc*).

In the case below, Medinol appealed based on five asserted errors in claim construction. One of these errors broadened the claim, and the Federal Circuit considered this error and affirmed the district court's ruling. App. 14a-15a. The other four asserted errors narrowed the claims by adding extraneous features to the claims that were not required by either the specification or the prosecution history. The Federal Circuit treated these errors as relating only to the infringement issues, which it did not need to review, because it was affirming the district court's decision denying JMOL on the issue of obviousness. *Id.* at 13a, 14a. The Federal Circuit dismissed any need to review Medinol's new trial motion on the obviousness issue, assuming that any errors which narrowed the claims could relate only to the infringement issues. *Id.* at 13a, 14a.

This reasoning ignores the dramatic impact that the narrowing claim construction errors had on the obviousness issue put to the jury. The district court's narrowing claim construction errors allowed Cordis to misdescribe and trivialize Medinol's invention before the jury by diverting the jury's attention from the true and full scope of the invention and focusing it instead on extraneous trivial requirements concocted by Cordis and imported into the claims by the district court. Instead of focusing on the differences in the claimed invention

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1999) ("Where jury instructions create an erroneous impression regarding the standard of liability, it is not harmless error because it goes directly to the plaintiff's claim, and a new trial is warranted." (citations omitted)).

which distinguished it from prior stents like the Palmaz-Schatz stent and from prior patents and publications in the prior art, all of which had been previously considered by the patent examiner during prosecution, Cordis was able to focus the jury's attention on the improperly added requirement that one component of the design be aligned "generally horizontally" or "longitudinally" parallel to the stent axis, and to characterize the BX Velocity as a completely different technology because the analogous component in the BX Velocity was "diagonal," and not aligned "generally horizontally" or "longitudinally" parallel to the stent axis. C.A. App. A2799-811.

This severely prejudiced Medinol because, as this Court stated over a century ago, it is fundamental that the jury in a patent trial should be properly charged as to the full and accurate scope of the patented invention:

> Our conclusion upon this part of the case, therefore, is, that the question of infringement, arising upon a comparison of the Royer patent and the machine used by the defendants, should be submitted to the jury, *with proper instructions as to the nature and scope of the plaintiffs' patent as hereinbefore defined*, and as to the character of the defendants' machine.

Coupe v. Royer, 155 U.S. 565, 580-81 (1895) (remanding for new trial where interpretation of the patent given by trial judge to jury was erroneous) (emphasis added); *see also Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1353 (Fed. Cir. 1999) ("The claims, properly interpreted, define the scope of the invention and allow the trial court to determine whether the claimed invention would have been obvious in light of the prior art.").

B. The District Court's Claim Construction Errors, Which the Federal Circuit Refused to Review, Had the Effect of Eliminating Important Objective Evidence of Nonobviousness.

The district court's narrowing claim construction errors also had a dramatic impact on the objective evidence of nonobviousness presented to the jury. These errors permitted Cordis to argue that its BX Velocity stent did not infringe, which inverted the impact of important objective evidence of nonobviousness under the "secondary considerations" prong of the Graham analysis. *See Graham*, 383 U.S. at 17-18.[15] Had the district court properly construed the claims, Medinol would have been entitled before trial to summary judgment that the BX Velocity literally infringed, and its commercial success would have inured to the claimed invention – not to something Cordis successfully urged was different from the claimed invention based on the erroneous requirements added to the claims by the district court.[16] This would have significantly bolstered the impact of Medinol's objective evidence of nonobviousness because it would have appeared to the jury that Cordis, after deciding not to acquire Medinol's technology, and then repeatedly failing to develop its own commercially acceptable stent, was ultimately obliged to appropriate Medinol's invention to regain its market share, which it did with the very successful BX Velocity stent. The district court's claim construction errors

15. *See also Ruiz*, 234 F.3d at 667 (Federal Circuit precedent "clearly hold[s] that secondary considerations, when present, must be considered in determining obviousness."); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983):

> Indeed, evidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decision maker remains in doubt after reviewing the art.

16. Cordis does not dispute that if the claims were construed as Medinol urged, the BX Velocity would literally infringe.

completely eviscerated the impact of this crucial objective evidence of nonobviousness because, based solely on the erroneous claim construction, Cordis could successfully argue that it did not infringe, and that it did not practice Medinol's invention but rather its own different invention.

The importance to the obviousness inquiry of objective evidence showing adoption and recognition of the invention has been relied on before by this Court to uphold a patent "[d]espite the fact that each of the elements of the [invention] was well known in the prior art." *See United States v. Adams*, 383 U.S. 39, 43-44, 49, 51-52 (1966) (relying on objective evidence of nonobviousness, including commercial success, tribute by experts, problems with the prior art, and advantages over the prior art).[17]

C. The Jury Verdict Upholding Another Claim Strongly Indicates that the District Court's Claim Construction Errors, Which the Federal Circuit Refused to Review, Likely Changed the Jury Verdict on the Obviousness Issue.

The prejudicial impact of the district court's claim construction errors is especially clear in this case, because the jury upheld the validity of one of the claims which was asserted against a different Cordis stent – the Corinthian stent. Unlike the commercially more important BX Velocity stent, the Corinthian stent (which was for peripheral instead of coronary applications) could not be distinguished from the

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17. *See also, e.g.*, *Advanced Display Systems, Inc. v. Kent State University*, 212 F.3d 1272, 1285-86 (Fed. Cir. 2000) (ordering new trial on obviousness because evidence of copying and failure of accused infringer to design a non-infringing device were withheld from jury); *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 679-80 (Fed. Cir. 1988) (reversing obviousness judgment in part because copying evidenced nonobviousness); *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579-81 (Fed. Cir. 1997) (reversing obviousness judgment in part because commercial success of infringing product evidenced nonobviousness).

invention based on the absence of the extraneous alignment requirement improperly added to the claims by the district court. The Corinthian stent was found to infringe, and Cordis elected not to appeal the finding of validity and infringement for the claim asserted against the Corinthian. Thus, in the case of the Corinthian, Cordis could not avoid the impact of objective evidence showing that Cordis had adopted Medinol's invention after evaluating it and failing to develop replacement designs of its own. On that record, the jury found that claim not obvious.

In contrast, for the claims asserted against the BX Velocity, Cordis was able to avoid the impact of the important objective evidence of nonobviousness by denying infringement and denying on the same basis that it had been forced to adopt Medinol's invention after its own failures. The jury found those claims not infringed by the BX Velocity, and found them all invalid, even though one claim was extremely close to the claim upheld, and there was no evidence presented that related in any way to the minor differences.

This otherwise irreconcilable difference in the jury's verdict vividly shows the dramatic importance to the verdict of the objective evidence of nonobviousness, and the extremely prejudicial impact of the district court's narrowing claim construction errors, which permitted Cordis to avoid the impact of such evidence entirely.

D. There Is No Basis for the Federal Circuit's New Legal Presumption that Claim Construction Errors Which Narrow the Claims Must be Harmless with Respect to the Obviousness Issue.

The Federal Circuit's conclusion that the ignored claim construction errors related only to infringement and not to obviousness was based on its erroneous and unexplained legal presumption that errors which have the effect of making the claims narrower cannot affect obviousness, because if a

narrow claim is obvious, a correctly construed broader claim embracing it would also be obvious. This superficial conclusion is plainly flawed. While a broader claim may increase the scope of the applicable prior art,[18] it is neither logical nor fair to hold such a claim invalid merely on the ground that a narrower claim was found invalid, unless the narrower claim was found invalid on a fair and proper record with all applicable evidence, including important objective evidence of nonobviousness. properly before the jury. In this case, erroneously limiting the invention to trivial features of the invention belittled it, excluded most of the commercial success that would have otherwise inured to it, and avoided the tribute Cordis paid to it by later adopting it after its own failures.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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18. This was not the case here, because no additional prior art would have become relevant had the district court correctly construed the claims.